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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,885	07/12/2001	Massi E. Kiani	MASIBP.013A	3598

20995 7590 07/13/2006

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EXAMINER	
RUHL, DENNIS WILLIAM	

ART UNIT	PAPER NUMBER
3629	

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/904,885	KIANI, MASSI E.	
	Examiner	Art Unit	
	Dennis Ruhl	3629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 25-31* is/are pending in the application.

4a) Of the above claim(s) *29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,25-28,30,31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's response of 4/27/06 has been entered. The examiner will address applicant's remarks at the end of this office action.

1. Newly submitted claim 29 is directed to an invention that is independent or distinct from the invention originally elected for the following reasons: In response to an election of species requirement setting forth 3 distinct method claim groups, applicant previously elected to prosecute the invention of Group I, which was the method of using a blood pressure monitor. No apparatus claims drawn to a "dual mode patient monitor" were presented for examination until after a first action on the merits. If apparatus claims were presented earlier, they would have been subject to a restriction requirement. The reasoning is that it is an undue burden on the examiner to have to search for specific structure of the apparatus and to search for a method of using a blood pressure monitor, where the specific structure is not required. In the instant case the blood pressure monitor can be used in a different method, such as by just using the non-continuous configuration without using the continuous configuration. The apparatus claims are classified in class 604 and the instant examiner works in class 705, which is a method class. If applicant desired to have the apparatus claims examined, then they should have been presented earlier.

Since applicant has received an action on the merits for the originally elected invention, this invention has been constructively elected for prosecution on the merits. Accordingly, claim 29 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-13,25-28,30,31, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

For claim 1, the language "wherein during the non-continuous configuration, the blood pressure monitor is not primarily seeking to determine, initialize, or calibrate continuous measurements" does not find support in the specification as originally filed and is considered to be new matter. The instant specification on page 2 states "*and a cuff for establishing a baseline blood pressure measurement to be used to calibrate continuous blood pressure measurements*". Page 7 states that "*the monitor 106 can operate the inflatable cuff 104 in the manner described above to generate a baseline measurement of the blood pressure to be used to calibrate an arterial line that can be connected between patient 102 and the monitor 106*". Page 8 states "*After the sensor 202 is attached to the patient 102 and is connected to the monitor 106, the inflatable cuff 104 is operated as described above to provide a baseline measurement of the patient's blood pressure. The baseline measurement is used to calibrate the noninvasive continuous mode measurements made using sensor 202*". Page 9 also

makes mention of the fact that the non-continuous measurement is used to calibrate the continuous mode. The specification as originally filed does not provide support for the newly added claim language and the specification actually makes numerous references to the fact that the non-continuous mode is used for calibration contrary to the newly added claim language. The newly added claim language contradicts what the specification teaches, is not supported by the specification as originally filed, and is found to be new matter.

Also found to be new matter for claim 1 and present in claim 25 is the language reciting that the monitor is capable of operating in the non-continuous configuration to monitor a patient during an entire time the patient is to be monitored. Because the non-continuous configuration is only able to monitor a patient at discrete intervals and is not capable of continuous monitoring, it is not possible to monitor the patient for the entire time as claimed with the non-continuous configuration and the specification as originally filed never disclosed that the non-continuous configuration was capable of monitoring an for entire time as claimed.

Applicant has provided no showing of where the specification supports the newly added claim language and if applicant traverses the new matter rejection the examiner requests that applicant point out where support can be found in the specification as originally filed.

4. Claims 1-13,25-28,30,31, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. .

For claims 1,25, applicant has claimed that the monitor is capable of operating in the non-continuous configuration to monitor a patient during an entire time the patient is to be monitored. The examiner finds this to be an impossible situation and concluded that one of skill in the art would not know how to make the non-continuous configuration so that so that the patient can be monitored "the entire time". The claim language requires that the patient be monitored an entire time the patient is to be monitored. Because the non-continuous configuration is only able to monitor a patient at discrete intervals and is not capable of continuous monitoring, it is not possible to monitor the patient for the entire time as claimed with the non-continuous configuration. Undue experimentation would be involved for a person skilled in the art to figure out how to make the non-continuous configuration monitor the patient an entire time when the non-continuous configuration is not capable of monitoring the entire time.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-13,25-28,30,31, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For claim 1, the examiner is not clear as to what applicant is attempting to recite by the language "*wherein during the non-continuous configuration the blood pressure monitor is not primarily seeking to determine, initialize, or calibrate continuous measurements*". Applicant is claiming what the monitor is not primarily seeking to do, not what is the monitor seeking to do, so it is not clear as to what this language means. Also not clear is what the scope of the language is as far as the language "*not primarily seeking*" goes. This appears to allow for the non-continuous configuration to be used for calibration as long as that is not the primary reason for using the non-continuous configuration. Does this language allow for the use of the non-continuous configuration for calibration or is this excluded from the claim scope? This language is considered indefinite. With respect to the language "*when the continuous blood pressure sensor signal is received, enabling operation of the blood pressure monitor in a continuous configuration*", the examiner does not see how this is possible. To receive the continuous sensor signal, the monitor must first be enabled so that the signal can be received. The sensor signal cannot come before the monitor is set up to receive the signal. This portion of the claim is indefinite because it appears to be reciting a situation that is not possible and one wishing to avoid infringement would not know what this portion of the claim means.

For claim 25, the language "during said use as a non-continuous blood pressure entire time" makes no sense and is considered indefinite. This portion does not even read grammatically correctly. What does this mean?

For claim 28, what is the enablement device that is claimed here? It is not clear from a reading of the specification what the scope of the term "enablement device" is. What does this mean? The examiner is not sure what this limitation is and is questioning whether or not this limitation is actually new matter, but until it is known what it is, the examiner cannot determine whether or not it is new matter.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4,8-13,25-28,30,31, are rejected under 35 U.S.C. 102(b) as being anticipated by Caro (6045509).

For claim 1,12,13, Caro discloses a method of using a continuous multi mode blood pressure monitor 100 that also has the ability to do non-continuous measurements. The monitor has a sensor input as claimed (where the sensor cable connects to the monitor). The cuff (calibration device) is 110 and the sensor is the combination of 202 and 210. Caro discloses that the measurement from the blood pressure cuff can and is used to provide an initial calibration, see column 4, lines 36-40. Concerning the claimed steps, Caro discloses the step of using the monitor in a non-continuous configuration to provide non-continuous measurements. This is interpreted to be the use of the inflatable cuff prior to enabling the continuous configuration. With respect to the language reciting that the monitor is not primarily seeking to determine,

initialize, or calibrate continuous measurements, this is just a recitation of the reason why the step of using the non-continuous configuration is being performed. This language is noted but is not changing the fact that the only step recited so far in the claim is the use of the non-continuous configuration, which is found in Caro. Reciting a different reason for doing the same step as the prior art is not going to distinguish over the prior art that discloses the same step. Caro disclose the use of the monitor in the continuous configuration to provide continuous measurements as claimed. With respect to the language at the end of the claim that recites the non-continuous configuration as being capable of monitoring the patient an entire time, the examiner refers applicant to column 6, lines 16-21, where it is stated that when the use presses the calibration button, the display 105 displays the current blood pressure (non-continuous) and the time elapsed from the last measurement. This satisfies what is claimed because if one wanted to do so, they could repeatedly press the calibration button and acquire a blood pressure measurement one after another for the entire time the patient was being monitored. Caro discloses this ability, which is all that this portion of the claim is reciting.

For claim 2, pressure is applied to the inflatable cuff, which satisfies what is claimed.

For claims 3,4, see column 4, lines 44-52.

For claim 8, see the figures where the claimed limitation is shown.

For claims 9,10, the sensor 202/210 is non-invasive as claimed. Caro discloses the limitations of claim 10 because that is how the sensor 202/210 is disclosed as

working. The sensor excites a perturbation in the blood and senses an effect of the perturbation.

For claim 30, the recited attaching of a component to the monitor to change operation from non-continuous to continuous is taken to be the attaching of the continuous sensor and associated cables/lines to allow the continuous mode to operate. If no continuous sensor is connected to the monitor, then it will not work in the continuous configuration.

For claims 11,31, see column 4, line 59, where the cuff is referred to as a calibration device. Column 6, lines 16-21 disclose the use of the calibration device during the use of the continuous configuration as claimed.

For claims 25-28, Caro discloses the providing of a blood pressure monitor that can be used in a non-continuous configuration and a continuous configuration (by utilizing a continuous sensor as claimed). The claim recites the providing of a monitor that is capable of non-continuously monitoring blood pressure of a patient during an entire time the patient is to be monitored. Caro discloses this ability because if one wanted to do so, they could use the inflatable cuff 110 to obtain non-continuous blood pressure measurements. The only other limitation is the providing of the monitor for use as a continuous monitor, which is disclosed by Caro. Caro discloses the providing of a monitor as claimed.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro et al. (6045509) in view of Wohltmann et al. (5904654).

For claims 5-7, Caro discloses the invention substantially as claimed. Caro does not disclose that the sensor includes an exciter and a transducer, where the exciter and transducer are integrated into one unit, which is a wristband. Wohltmann discloses an exciter/detector unit that is incorporated into one unit in the form of a wristband. The one-piece unit is an improvement over a two-piece unit and allows for convenient attachment to the body. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide Caro with a one piece unit as disclosed by Wohltmann so that instead of having to connect two units to the patient (as in Caro), one only has to connect the wristband of Wohltmann.

11. Applicant's arguments filed 4/27/06 have been fully considered but they are not persuasive. With respect to the argument that Caro is using the non-continuous mode to calibrate the continuous mode and that the instant invention does not do that, the examiner disagrees because the specification discloses in more than one place that the non-continuous mode is used to calibrate the continuous mode. The language added to the claims has been found to be new matter and the argument applicant has presented

is also based on new matter and contradicts the instant specification itself. Caro does teach two modes of operation, one non-continuous and one being continuous, just like the instant invention. The examiner does not see anything patentable in the presently pending claims.

For the dependent claims 2-13,26-28,30,31, applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. The statement that the dependent claims are patentable because they recite "additional features" is nothing more than a general allegation of their patentability. The examiner also notes that applicant did not even mention the 103 rejection of Caro in view of Wohltmann and has provided no traversal at all for this rejection. Absent any traversal, the examiner finds the 103 to be proper and the obviousness statement by the examiner to be proper. If applicant disagreed with the 103 rejection of Caro in view of Wohltmann and the modification set forth by the examiner, then a traversal of some kind should have been presented.

With respect to applicant's statement that they desire an interview with the examiner in the event the case is not found to be allowable and further issues remain to be resolved, at this point the examiner does not feel an interview would be productive or efficient due to the numerous issues now present in this application that applicant has not yet had a chance to look over. The request itself is found improper in that applicant is not following the MPEP guidelines. The examiner refers applicant to MPEP 713

where it is stated "*When applicant is initiating a request for an interview, an "Applicant Initiated Interview Request" form (PTOL-413A) should be submitted to the examiner prior to the interview in order to permit the examiner to prepare in advance for the interview and to focus on the issues to be discussed. This form should identify the participants of the interview, the proposed date of the interview, whether the interview will be personal, telephonic, or video conference, and should include a brief description of the issues to be discussed.*" None of this has been done. The examiner requests that applicant follow MPEP 713 when requesting an interview so that the issues to be discussed (proposed amendments or proposed arguments) are clear and an agenda of some kind is set forth.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dennis Ruhl whose telephone number is 571-272-6808. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss can be reached on 571-272-6812. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DENNIS RUHL
PRIMARY EXAMINER